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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/751,059

12/29/2000

James R. Baker JR.

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/751,059	BAKER ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 134-184 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 134-137, 139-157, 159-169 and 171-185 is/are rejected.
- 7) ☒ Claim(s) 138, 158 and 170 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 3/13/06; request for extension of time filed 3/13/06.

Original claims 1-70 were canceled by the amendment filed 9/21/04 at which time claims 71-130 were added. Claims 71, 93, 104, 110, 111 and 121 were amended, claims 100, 105-109, 112, 115-120, 122-130 were canceled, and claims 131-133 were added, by the amendment filed 2/03/05. The amendment filed 4/29/2005 further amended claims 71, 93 and 104. The amendment filed 3/13/06 cancels the rest of the claims from 4/29/2005 and added new claims 134 to 185. Thus, claims 134-185 are pending.

The New claims: New claims 134 and 155 are the same as previously presented claims 71 and 93 except that item 5 (previously e)) of new claims 134 and 155 contain language that the combination of 1 through 5 results in an antimicrobial composition before the addition of the halogen containing compound. New claim 165 and previously presented claims 104 are the same except in the new claim; item b (previously e) is separated from items a₁-a₄ (previously a-d). New claims 182 and 183 are the same as previously presented claims 121 and 131 except that the new claims state that the combination of the oil phase, the aqueous phase, the alcohol and the surfactant is antimicrobial. In all these claims, 134, 155, 165, 182 and 183, the combination according to the claims occur under conditions that make the composition antimicrobial itself.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 134-137, 139-141, 143-146, 148-150, 152-157, 159-165, 168, 169, 173, 175-178, 180 and 181 are rejected under 35 U.S.C. 102(b) as being anticipated by Spitzer et al. (US 3,912,666). Claim 180, which is dependent on claim on claim 165 is a new claim and is included in this rejection.

Spitzer discloses oil-in-water emulsion (abstract, column 6, line 34) that contains halogen compound such as vinyl chloride, methyl chloride, propellants and Freon and halogenated solvents (column 6, line 66 to column 7 line 9; column 8, lines 57-64), oil phase and aqueous phase (column 9, lines 31-42), surfactant such as sodium dodecyl sulfate, polyethylene glycol esters, cetyltrimethylammonium bromide (column 10, lines 16-67), ethyl alcohol or methyl alcohol or isopropyl alcohol or glycerol (column 11, lines 15-19). Spitzer's formulation may contain plasticizers such as tricresyl phosphate, butyl glycolate, citrate and phthalate (column 9, line 1-5). Cetyltrimethylammonium bromide is also a halogen-containing compound, of the type applicants regard as halogen-containing compound, that has deodorizing and antiseptic properties (column 12, lines 18 and 19). Spitzer discloses that the oil-in-water emulsion composition is topically applied as cleansing, conditioning, coating, lubricating agents, personal washing, laundering, dishwashing, shampoos, shaving cream, hair color and rinses (column 12, line 58 to column 13 line 13); Spitzer's oil-in-water emulsion composition is also useful as furniture and shoe cleaners and polish (column 13, lines 14-20). Spitzer's oil-in-water emulsion composition may also contain medicaments such as antimicrobial agents (column 13, lines 22-

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61). Regarding medical device, applicants' specification in paragraph [0091] of the published application defines medical device as a "drug delivery devices" and Spitzer incorporates medicaments such as histamines, sulfa drugs, antibiotics, hormones, vitamins, antimicrobials agents and procaine (column 13, lines 22-53). See also Examples 1-2. The aqueous phase in Spitzer is about 10% to about 75% by weight of the emulsion and by corollary (claim 17), the oil phase would be from about 90% to about 25% by weight of the emulsion and since the density of the emulsion would not be drastically different than the density of water at 1, the weight percent would approximate volume percent. Shampoos and shaving creams are topical compositions and thus meet the limitation of claim 180. Spitzer meets the limitations of the claims.

Response to Arguments

3. Applicants' arguments filed 3/13/06 have been fully considered but they are not persuasive.
4. **Spitzer anticipates claims 134-137, 139-141, 143-150, 152-157, 159-165, 168, 169 (previously claims 71-74, 76-78, 80-87, 90-95, 97-99, 101-104, 113 and 114). The response also applies to the argument as the argument applies to claims new claims 173, 175-178, 180 and 181.**

Applicants argue:

- a) that the combination of oil phase, aqueous phase, alcohol, surfactant and organic phosphate solvent is antimicrobial, that the antimicrobial effect is a physical property of the composition and element of the conditions of making the composition;

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- b) that the specification provides ample guidance for selecting the appropriate type and amount of the recited components to achieve the claimed properties; that these properties are not inherent in emulsions containing the recited ingredients;
- c) that the specification provides examples of emulsion having the recited ingredients that are not anti-pathogenic, so that finding the recited ingredients in a prior art reference does not imply the claimed properties,
- d) that Spitzer does not teach or suggest the claimed compositions and methods,
- e) that “the emulsions of Spitzer are never said to be combined under such conditions such that they are antimicrobial without the inclusion of additional medicaments” and that “while the present invention may, in some embodiments, incorporate additional compounds, it does so when the oil-in-water emulsion is combined under conditions such that the oil-in-water emulsion itself is antimicrobial in the absence of added compounds.”

Response:

Regarding a), it is noted that the claimed composition, for example, claim 134, comprises combination of oil phase, aqueous phase, alcohol, surfactant and organic phosphate and composition/product and its properties are not mutually exclusive so that same compositions would necessarily have the same properties because a composition and its properties are inseparable; applicants support this position when applicants state that the antimicrobial effect is a result of the property of the composition. Spitzer discloses a composition comprising oil phase, aqueous phase, surfactant and organic phosphate as described above. The comprising language of the claims is open and does not exclude the antimicrobial agents disclosed by

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Spitzer. Regarding the conditions of making the composition as per applicants, it is noted that applicants appear to rely on limitations that may be in specification and although, the claims are interpreted in light of the specification, limitations from the specification cannot be read into the specification. Thus, the features in the specification upon which applicant relies (conditions for making the composition found in the specification) are not recited in the rejected claim(s). See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding b) the guidance provided by the specification does not change the properties of the composition and further applicants are relying of features that are not in the claims.

Regarding c) it is noted that applicants appear to raise issues that some compositions are antimicrobial and others are not antimicrobial and the scope of the claims centers around a composition that comprises oil phase, aqueous phase, alcohol, surfactant and organic phosphate and even if the process of making the composition is specifically recited in the claims as by product-by-process, in the absence of structural difference imparted by the method, the prior art composition which is structurally the same would have the same properties.

Regarding d) Spitzer discloses the instant composition as stated in the rejection and Spitzer discloses the method of preparing the composition, which is emulsification of the mixture to form an emulsion.

Regarding e) it is noted that no “such conditions” are identified by the claims and the conditions under which the composition is formed is really conditions not recited in the claims. The comprising language of the claims is open.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The rejection of claims 121 and 131-133 (now claims 182, 183-185) under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,015,832) is withdrawn because although Baker discloses the use of sodium hypochlorite as killing spores, Baker does not disclose the hypochlorite (halogen containing compound) as part of its composition but rather, Baker discloses the hypochlorite as a toxic and irritating chemical that is effective in killing *B. anthracis* spores. In response to applicants iteration that the rejection over Baker under 35 USC 103 was addressed in applicants' response filed 4/29/05, it is noted that applicants addressed the rejection under 35 USC 102 and not the 103. Please, also note that claims 121 and 131 are independent claims. However, applicants'

7. The rejection of claims 104, 110, 111, 113 and 114 (now claims 165-169) under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Homola et al. (US 5,961,958) or Hill (US 5,380,530) is withdrawn because applicants' argument is persuasive in that the ethanol or methanol solvent in Homola is non-existent after evaporation and also that the generic or broad disclosure of an emulsion does not lead one to coat the chewing gum with oil-in-water emulsion.

8. Claims 182, 183-185 (previously claims 121 and 131-133), 134-137, 141, 142, 145, 146, 147, 151, 155-157, 165-169, 171-176 and 179-181 are rejected under 35 U.S.C. 103(a) as being

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unpatentable over Baker, Jr. et al. (US 6,015,832) and Boucher (US 3,968,250) or Simmons et al. (US 5,405,602).

Baker discloses methods of inactivating bacterial spores where the method comprises contacting the bacteria or bacteria containing surfaces and objects with an oil-in-water emulsion composition; the oil-in-water emulsion composition comprises a surfactant such as sodium dodecyl sulfate, organic phosphate based solvent such as tri-n-butyl phosphate, carrier oil and oligopeptides (abstract, column 2, lines 14-47, column 3, lines 5-15). The oils used are water immiscible oils such as squalene oil, fish oils, canola oil, rapeseed oil, corn oil and flavor oils (column 2, lines 53-57); the surfactants are TWEEN, TRITON, which is a polyoxyethylene polyoxyethanol (column 3, lines 1-4); Baker's formulation may also contain alcoholic solvent (column 3, lines 13-15). Baker also discloses method of treating a subject by applying pharmaceutically suitable bacteria inactivating composition topically to skin surfaces, mucous membranes, oral surfaces and to wounds and the composition will typically be a cream, gel, spray or mouthwash (column 3, lines 21-29). Furthermore, Baker discloses that the emulsion composition can be used to inactivate bacterial spores by topical application of the emulsion to skin or mucous membranes (column 3, lines 29-39) and can be used to inactivate bacteria and bacterial spores on surfaces that come in contact with the human and vehicles and instruments are examples of surfaces that can be decontaminated (column 3, lines 40-49). Baker discloses evaluating the efficacy of the composition on bacterial spores by biological assay, and adds sterile saline to either the culture or the emulsion (column 9, lines 3-25 and column 10, lines 23-53).

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Baker also discloses that the emulsion is used to inactivate bacteria and bacterial spores on surfaces that come in contact with humans (column 3, lines 40-45). Furthermore, Baker indicates that the emulsions may be combined with edible substances for swallowing (column 5, lines 33-45). Since the emulsion is capable of inactivating bacteria or bacterial spores on any surface that it comes in contact with, it stands to reason, the emulsion may also do the same when it is in contact with edible substance. Baker does not disclose halogen-containing compound. But, Boucher discloses that surfactants such as cetylpyridinium cationic surfactant, kills bacterial spores (Table II). Simmons discloses a composition containing halogen-containing compound such as cetylpyridinium chloride that inactivates or kills bacterial spores (column 10, lines 54-59, 60-68; column 11, lines 38, 45-55, 60-65; column 12, lines 13-18 and line 26 to column 13 line 10). The compositions of Baker, Boucher and Simmons inactivate or kill bacterial spore.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a combined composition of Baker and Boucher or Baker and Simmons to form a third composition with the expectation that the third composition would inactivate or kill bacterial spores. Specifically, the addition of a cationic surfactant such as cetylpyridinium chloride would act in synergy with the composition of Baker that is already determined to kill or inactivate bacterial spore. The idea of combining them flows logically from their having been individually taught in the prior art. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

9. Applicants' arguments filed 3/13/06 have been fully considered but they are not persuasive.

Regarding applicants' argument that there is no suggestion to combine Baker and Simmons, it is noted that the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation flows from the fact that the two compositions are used to inactivate or kill bacterial spores and the combined composition would be expected to successfully inactivate or kill bacterial spores. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Regarding applicants' argument that conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence," it is noted that conclusory statement was not made. Rather is proper to combine two compositions to form a third composition that would be used the same purpose as is the case in *in re Kerkhoven*.

Regarding applicants' argument about assertion, it is noted that the motivation to combine the references of Simmons and Baker is that each of the compositions is used to kill or inactivate bacterial spores; the motivation flows that the combined composition is expected to

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kill or inactivate bacterial spores and that is the disclosure of Simmons and Baker (the rejection above specifically state that the prior art references disclose compositions that are used to kill or inactivate bacteria).

Regarding hindsight reasoning by the examiner, it is noted that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The prior art discloses compositions that are used to inactivate or kill bacteria and this is not hindsight.

Regarding the non-aqueous nature of Simmons, it is noted cetylpyridinium chloride and glutaraldehyde can be made in aqueous medium (see the composition of Boucher cited above, abstract of Boucher).


10. Claims 138, 158 and 170 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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